

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Ghigo et al. Confirmation No.: 1304  
Application No.: 10/595,485 Art Unit: 1646  
Patent No.: 7,825,090  
Filed: September 6, 2007 Examiner: G. Chandra  
Title: USE OF GHRELIN AND UNACYLATED GHRELIN  
COMPOSITIONS IN INSULIN-RELATED DISEASE CONDITIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. §§ 1.702-1.705**

Dear Sir:

The Issue Notification mailed on October 13, 2010 for the application referenced above recites a 151 day patent term adjustment. Applicants believe that the application is entitled to 508 days of term adjustment, and hereby request reconsideration of the patent term adjustment.

Applicants believe the total patent term adjustment under 37 C.F.R. §§ 1.702-1.704 should be the total of:

(1) 155 days under 37 C.F.R. §§ 1.702(a)(1-2) and 1.703(a)(1-2) for the Patent Office delay in examination, and more specifically:

(a) 148 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1) for the Patent Office delay in issuing a first office action 14 months after the filing date on which the application fulfilled the requirements of 35 U.S.C. 371 in an international application; and

(b) 7 days under 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2) for the Patent Office delay in responding to Applicants' reply within 4 months after the date on which the reply was filed;

(2) 557 days under 37 C.F.R. §§ 1.702(b) and 1.703(b) for the Patent Office delay in issuing the patent after April 24, 2009 (three years from the filing date) until the issue date of the patent (November 2, 2010); and

(3) minus any Applicants' delay (197 days) under 37 C.F.R. § 1.704 and any overlapping days (7 days) between the periods (1) and (2) under 37 C.F.R. § 1.703(f).

The periods (1) and (2) overlap by 7 days under 37 C.F.R. § 1.703(f). *See Wyeth v. Dudas*, 88 U.S.P.Q.2d 1538 (D.D.C. 2008). Thus, the total adjustment based on (1), (2) and (3) above would be 508 days.

The additional days of patent term adjustment are requested under 37 C.F.R. §§ 1.702(b) and 1.703(b) for the following reason.

37 C.F.R. 1.702(b) states:

Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under ... the national stage *commenced* under 35 U.S.C. 371 (b) or (f).... (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences."

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty.

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with.

35 U.S.C. § 371(f) is applicable when an applicant files a request for early processing of an international application. Without such a request, the U.S. national stage commences under 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. The term "treaty" means "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. §351(a). According to the Patent Cooperation Treaty articles 22(1), 22(2) and 39(1)(a), the term "the applicable time limit" is "the expiration of 30 months from the priority date." Thus, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences under 35 U.S.C. § 371(b). Accordingly, the actual filing date of a U.S. notational stage application filed under 35 U.S.C. § 371 is the date which is 30 months from the priority date of the international application.

The instant application commenced under 35 U.S.C. § 371 on April 24, 2006, which is the 30 month date from the priority date of October 24, 2003, and therefore should have issued by April 24, 2009.

37 C.F.R. § 1.703(b) states in pertinent part:

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under . . . the national stage commenced under 35 U.S.C. 371 . . . and ending *on the date a patent was issued* . . . (emphasis added)

Therefore, the relevant period of delay in issuing the patent began on April 24, 2009 and the patent issued on November 2, 2010, our calculations show that the application should receive an additional 357 day term adjustment, for a total of 508 days.

Applicants did not file a request for continued examination under 35 U.S.C. § 132(b) during prosecution of the instant application. The instant application was never involved in an interference or maintained in a sealed condition under 35 U.S.C. § 181. Applicants did not file a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. § 134 and 37 C.F.R. § 41.31 for the instant application. The instant application is not subject to a terminal disclaimer. According to Applicants' calculations, there should be no other additional deduction from the calculated patent term adjustment due to delay by Applicants.

The fee for the Request for Consideration is being paid herewith via credit card. We believe no other fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 08-0219, under Order No. 0290494.00122US1 from which the undersigned is authorized to draw.

Respectfully submitted,

Date: November 4, 2010

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